DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 19, 2017

Intuitive Surgical, Inc.
% Ms. Cindy Domecus
Principal, Domecus Consulting Services, LLC & Chief Regulatory Advisor, Intuitive Surgical
Domecus Consulting Services LLC
1171 Barroilhet Drive
Hillsborough, California 94010

Re: K171632
Trade/Device Name: da Vinci Xi Surgical System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: NAY
Dated: August 11, 2017
Received: August 15, 2017

Dear Ms. Domecus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171632

Device Name

da Vinci Surgical System, Model IS4000, and EndoWrist Instruments and Accessories

Indications for Use *(Describe)*

The Intuitive Surgical Endoscopic Instrument Control System (da Vinci Surgical System, Model lS4000) is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endloscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, and delivery and placement of microwave and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use. It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary (21 CFR § 807.92(c))

I. SUBMITTER INFORMATION

Submitter: Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, CA 94086

Contact: Cindy Domecus, R.A.C. (US & EU)
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Date Summary Prepared: September 19, 2017

II. SUBJECT DEVICE INFORMATION

Device Trade Name: *da Vinci*® Surgical Systems, Model IS4000 and Model IS4200
Common Name: System, Surgical, Computer Controlled Instrument
Classification Name: Endoscope and Accessories (21 CFR §876.1500)
Regulatory Class: II
Product Code: NAY
Submission Type: Traditional 510(k)

III. PREDICATE DEVICE INFORMATION:

Predicate Device: Intuitive Surgical *da Vinci* Surgical Systems, Models IS4000 and IS4200 (K131861, K152578, K153276, K161178, K170713, K171294)
Intuitive Surgical *da Vinci* Surgical System, Model IS3000 (K081137, K123463, K090993)

IV. DEVICE DESCRIPTION:

This 510(k) is for expansion of the representative, specific procedures via labeling modification, to include the following additional representative, specific procedures under the previously cleared "general laparoscopic surgical procedures" indication for the *da Vinci Xi* Surgical System (K131861) and the *da Vinci X* Surgical System (K171294) : Colectomy (Right, Left, Transverse, Total, Hemi & Sigmoidectomy);[1] Small Bowel Resection; Rectopexy; Intersphincteric Resection (ISR); and Low Anterior Resection/Total Mesorectal Excision (LAR/TME) and Abdominoperineal Resection (APR). There are no changes to the technological characteristics of the cleared *da Vinci Xi or X* Surgical Systems proposed in this submission. The *da Vinci Xi and X* Surgical Systems, Models IS4000 and IS4200, are software-controlled, electro-mechanical systems designed for surgeons to perform minimally invasive surgery. The Model IS4000 and Model IS4200 Surgical Systems consist of a Surgeon Console, a Patient Side Cart (PSC), and a Vision Side Cart (VSC) and are used with an Endoscope, *EndoWrist* Instruments, and Accessories.

[1] "Colectomy" is already a cleared, representative, specific procedure under K131861. This application requests a revision to the labeling to specify "Right, Left, Transverse, Total, Hemi and Sigmoidectomy" colectomy procedures.

V. INDICATIONS FOR USE

The Intuitive Surgical Endoscopic Instrument Control System (*da Vinci* Surgical System, Models: lS4000 and IS4200) is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, and delivery and placement of microwave and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use. It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

Precaution for Representative Uses

The demonstration of safety and effectiveness for the representative specific procedures was based on evaluation of the device as a surgical tool and did not include evaluation of outcomes related to the treatment of cancer (overall survival, disease-free survival, local recurrence) or treatment of the patient's underlying disease/condition. Device usage in all surgical procedures should be guided by the clinical judgment of an adequately trained surgeon.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

There are no changes to the technological characteristics of the cleared *da Vinci* Xi or X Surgical Systems (IS4000 and IS4200) proposed in this submission.

VII. PERFORMANCE DATA

Pre-Clinical Animal Study Data

Animal performance data were provided in this premarket notification, including the results from seven (7) evaluations in a total of 32 animals demonstrating use of *da Vinci Xi* Surgical System in the following procedures: Nephrectomy, Pyeloplasty, Hysterectomy and Salpingectomy/Oophorectomy (Adnexectomy), Nissen Fundoplication, Colectomy, Mitral Valve Repair and Small Bowel Anastomosis. These data were previously submitted in support of clearance of the *da Vinci Xi* Surgical System (K131861), the *da Vinci Xi* Stapler 45 (K140553) and the *da Vinci Xi* labeling modification to add specific procedures under the gynecologic laparoscopic surgical procedures general indication (K152578); general thoracoscopic surgical procedures and thoracoscopically-assisted cardiotomy procedures indication (K153276); and urologic surgical procedures general indication (K161178). These data also support inclusion of the additional representative, specific procedures.

Clinical Study Data

Published clinical data support use of the *da Vinci Xi and X* Surgical Systems in the subject representative, specific procedures that fall under the cleared "general laparoscopic surgical procedures" Indication for Use. Clinical data were not provided for all of the representative, specific procedures. Instead, clinical data were provided only for the most complex/highest risk representative, specific procedures of Low Anterior Resection / Total Mesorectal Excision "LAR/TME" and Intersphincteric Resection "ISR" (referred to as the "umbrella" procedures). The published data on these "umbrella" procedures were deemed sufficient to cover the less complex/lower risk procedures (referred to as "covered" procedures), so published clinical data on the covered procedures were not provided.

Umbrella Procedures

Umbrella Procedure 1: Low Anterior Resection/Total Mesorectal Excision

Published clinical data were provided for the "Low Anterior Resection/Total Mesorectal Excision" umbrella procedure. Eleven (11) publications were identified for this umbrella procedure based on specific search criteria and filters. These publications included a prospective randomized controlled trial, meta-analyses, systematic reviews and large database comparative studies. A detailed summary of the published clinical data on this procedure is provided in **Tables 1A** and **1B** below.

The findings from the LAR/TME publications show that *da Vinci*-assisted procedures are:

- Mortality: associated with comparable mortality rates,
- Transfusions: comparable or lower blood transfusion rates and EBL volumes,
- Length of Stay: comparable or shorter lengths of hospital stay,
- Complications: comparable or lower complication rates,
- Surgical Margins: comparable rates of positive surgical margins
- Anastomotic Leak: comparable anastomotic leak rates; and,
- ED: comparable or lower erectile dysfunction ED[2] rates as compared to both open and laparoscopic surgical procedures.
- Operative Time: Increased operative times were associated with *da Vinci* procedures as compared to open and laparoscopic procedures. However, this increase was not associated with an increase in the mortality or complication rates.
- Urologic Function: Additionally, these publications reported comparable urologic function and comparable or lower conversion rates for *da Vinci*-assisted procedures as compared to laparoscopic procedures.

Umbrella Procedure 2: Intersphincteric Resection

Published clinical data were provided for the "Intersphincteric Resection" umbrella procedure. Two (2) publications provided ISR data. One (1) publication reported the results from a retrospective comparative cohort study and one (1) publication reported the results from a prospective comparative

cohort study. A summary of the published clinical data on this procedure is provided in **Tables 2A** and **2B** below.

The findings from the ISR publications show that *da Vinci*-assisted procedures are associated with:

- Mortality: comparable mortality rates,
- Transfusions: comparable blood transfusion rates and EBL volumes,
- Length of Stay: comparable lengths of hospital stay,
- Complications: comparable complication rates,
- Surgical Margins: comparable rates of positive surgical margins,
- Anastomotic Leak: comparable anastomotic leak rates,
- ED: lower erectile dysfunction ED rates; and,
- Continence: comparable or higher fecal continence rates[3] as compared to both open and laparoscopic surgical procedures.
- Operative Time: Increased operative times were associated with *da Vinci* procedures as compared to open and laparoscopic procedures. However, this increase was not associated with an increase in the mortality or complication rates.
- Urologic Function: Additionally, these publications reported comparable urologic function and comparable conversion rates for *da Vinci*-assisted procedures as compared to laparoscopic procedures.

Covered Procedures

The published data on the above cited LAR/TME and ISR umbrella procedures were extrapolated to support clearance of the following covered procedures:

- Colectomy (Right, Left, Transverse, Total, Hemi & Sigmoidectomy),[4]
- Small Bowel Resection,
- Rectopexy, and
- Abdominoperineal Resection (APR).

VIII. CONCLUSION

Based on the information provided in this premarket notification for expansion of the representative, specific procedures, the inclusion of the following additional representative, specific procedures under the *da Vinci Xi* and *X* Surgical Systems "general laparoscopic surgical procedure" indication is substantially equivalent to the predicate devices (*da Vinci Xi* and *X* Surgical Systems): Colectomy (Right, Left, Transverse, Total, Hemi & Sigmoidectomy);[4] Small Bowel Resection; Rectopexy; Intersphincteric Resection (ISR); and Low Anterior Resection/Total Mesorectal Excision (LAR/TME) and Abdominoperineal Resection (APR).

[4] "Colectomy" is already a cleared, representative, specific procedure under K131861. This application requests a revision to the labeling to specify "Right, Left, Transverse, Total, Hemi and Sigmoidectomy" colectomy procedures.

TABLE 1A: *da Vinci* vs. Open and *da Vinci* vs. Laparoscopic Low Anterior Resection/Total Mesorectal Excision

Publications	Sample Size (N)		Operative Time (minutes)	Estimated Blood Loss "EBL" (ml)	Length of Stay (days)	PostOp Complications (%)	IntraOp Complications (%)	Mortality Rate (%)	Transfusion Rate (%)
1. Midura (2015)	*da Vinci*	331	Not Reported	Not Reported	5	Not Reported	Not Reported	1.20	Not Reported
	Open	4403			6			1.70	
	Lap	5935			5			1.20	
2. Liao (2016)	*da Vinci*	498	191 -337.9	0 – 187.5[1]	6 – 10.8	25.7	Not Reported	1.1	4.6
	Open	576	124 – 273.8	120 – 275.48[1]	7 - 16	26.6		1.5	7.9
3. Somashekhar (2015)	*da Vinci*	25	310.3	165.14	7.52	0 / 0[2]	4	0	Not Reported
	Open	25	246.3	406.04	13.24	16/ 4[2]	0	0	
4. Lee (2015)	*da Vinci*	1043	202 – 396.5	45.7 – 188.8	2.9 – 11.9	Not Reported	Not Reported	Not Reported	Not Reported
	Lap	1181	158.1 – 298.8	59.2 – 229.2	3.9 – 13.5				
5. Lin (2011)	*da Vinci*	268	202 – 232.6	100 – 137.40	6.9 – 11.9	22.01	Not Reported	Not Reported	Not Reported
	Lap	393	158.10 - 208	127 – 150	8.7 – 9.8	19.34			
6. Memon (2012)	*da Vinci*	353	190.1 – 385.3	Not Reported	5.7 – 11.9	10.7 – 32.2	Not Reported	Not Reported	Not Reported
	Lap	401	168.6 – 315.0		6 – 14.4	18.9 – 27.1			
7. Sun Y (2016)	*da Vinci*	1217	Not Reported	Not Reported	5	16	Not Reported	0.40	Not Reported
	Lap	4700			5	19.1		0.76	
8. Sun Z (2015)	*da Vinci*	324	190.1 – 325.5	Not Reported	4 - 8	Not Reported	Not Reported	Not Reported	Not Reported
	Lap	268	190 - 280		3.6 - 10				
9. Trastulli (2012)	*da Vinci*	125	190.1 – 385.3	Not Reported	5.7 – 11.9	29.30	Not Reported	0	Not Reported
	Lap	156	158.1 – 297.3		6.6 – 14.4	23.10		0	
10. Xiong (2014)	*da Vinci*	554	202 – 309.7	100 – 200	6.5 – 11.9	10 – 32.4	Not Reported	0	Not Reported
	Lap	675	158.1 – 315	126.2 – 300	6 – 13.5	12.2 – 27.9		0	
11. Yang (2012)	*da Vinci*	300	190.1 – 296	100 – 200	5.7 – 11.9	10.7 – 32.2	Not Reported	Not Reported	Not Reported
	Lap	426	158.1 – 315	127 – 300	6 – 9.8	12.2 – 27.1			

[1]Intraoperative Transfusions were also reported (robotic cohort: 1.9 - 5.4%, open cohort: 0 – 12.4%)

[2]Minor and Major Complications Reported

TABLE 1B: *da Vinci* vs. Open and *da Vinci* vs. Laparoscopic Low Anterior Resection/Total Mesorectal Excision

Publications	Sample Size (N)		PSM Rate (%)	Urologic Function	Conversion Rate (%)	No. of Lymph Nodes Harvested	CRM / Positive CRM Rate (%)	DRM / Positive DRM Rate (%)	Anastomotic Leak Rate (%)	Erectile Dysfunction
1. Midura (2015)	*da Vinci*	331	4.30	Not Reported	Not Reported	71.6% ≥12	Not Reported	Not Reported	Not Reported	Not Reported
	Open	4403	6.10			66.3% ≥12				
	Lap	5935	4.70			68.7% ≥12				
2. Liao (2016)	*da Vinci*	498	Not Reported	Not Reported	Not Reported	17.4	8.41	2.08	6.63	Not Reported
	Open	576				16.5	8.62	2.02	4.51	
3. Somashakher (2015)	*da Vinci*	25	0	Not Reported	0	16.88	0	3.6 cm / 0%	0	18%[1]
	Open	25	0		N/A	15.2	0	2.4 cm / 0%	4	26%[1]
4. Lee (2015)	*da Vinci*	1043	Not Reported	3mo:3.6 - 8.36[4] 6mo: 3.5- 8[4] 12mo: 3.53 - 6[4]	1.19	10.3 - 20	Not Reported	Not Reported	0 - 20	3mo:3.8 – 8.0[2] 6mo:2.4 – 4.5[2]
	Lap	1181		3mo: 5.5– 11.7[4] 6mo: 3.2 – 8.2[4] 12mo: 4.2 - 8[4]	6.50	11.07 – 17.4			2.7 - 14	3mo: 5.9 - 13[2] 6mo: 4.5 – 6.8[2]
5. Lin (2011)	*da Vinci*	268	Not Reported	Not Reported	1.87	15.3	1.69%	2.8	Not Reported	Not Reported
	Lap	393			7.63	13.8	3.17%	3.6		
6. Memon (2012)	*da Vinci*	353	Not Reported	Not Reported	1.42	MD[5]:-0.9 [-1.94, 1.80]	3.1	2.0 -4.0	Not Reported	Not Reported
	Lap	401			7.73		3.2	2.0 – 4.5		
7. Sun Y (2016)	*da Vinci*	1217	7	Not Reported	8.22	16.8	4.76	3.5%	Not Reported	Not Reported
	Lap	4700	7		15.76	16.4	9.3	4%		
8. Sun Z (2015)	*da Vinci*	324	Not Reported	Not Reported	0	15	5	Not Reported	Not Reported	Not Reported
	Lap	268			7.94	14	5			
9. Trastulli (2012)	*da Vinci*	125	Not Reported	Not Reported	2.8	13.1 – 19.4	2.8	2 – 3.6	8	Not Reported
	Lap	156			6.7	15.9 - 17	4.0	2 – 3.8	6.3	
10. Xiong (2015)	*da Vinci*	554	Not Reported	Not Reported	1.08	10.3 – 19.4	2.74	1.9 – 2.8	4 - 11	3.3 – 5.5[3]
	Lap	675			5.19	11.1 - 17	5.78	2 – 4.5	2.7 - 14	16.6 – 43.3[3]
11. Yang (2012)	*da Vinci*	300	Not Reported	Not Reported	1.67	10.3 - 20	0 - 7.1	2 - 4	1.8 – 13.6	Not Reported
	Lap	426			7.98	11.1 - 21	0 – 8.8	2 – 4.5	2.7 – 10.2	

[1] Erectile dysfunction and retrograde ejaculation were assessed in all male patients during follow-up using the European Organization for Research and Treatment of Cancer (EORTC) questionnaire QLQ-C38. A total of 18 % of male patients in the RA group and 26 % in the OA group had sexual dysfunction features.

[2] Publications utilized IIEF Questionnaires

[3] One publication used a non-standardized questionnaire to assess ED and the other used the IIEF Questionnaire

[4] Publication reported the IPSS score for Urologic function.

[5] Mean difference reported with 95% confidence interval.

[6] PSM = Positive Surgical Margin

[7] CRM = Circumferential Resection Margin

[8] DRM = Distal Resection Margin

TABLE 2A: *da Vinci* vs. Open vs. Laparoscopic Intersphincteric Resection (ISR)

Publications	Sample Size (N)		Operative Time (minutes)	Estimated Blood Loss "EBL" (ml)	Length of Stay (days)	PostOp Complications (%)	IntraOp Complications (%)	Mortality Rate (%)	Transfusion Rate (%)
1. Park (2012)	*da Vinci*	40	235.5	45.7	10.6	15	Not Reported	0	0
	Lap	40	185.4	59.2	11.3	12.5		0	0
2. Kim (2014)	*da Vinci*	108	191	Not Reported	7	22.2	1.9	0	4.6
	Open	114	124		7.6	17.5	4.4	0	7.0

TABLE 2B: *da Vinci* vs. Open vs. Laparoscopic Intersphincteric Resection (ISR)

Publications	Sample Size (N)		PSM Rate (%)	Urologic Function	Conversion Rate (%)	No. of Lymph Nodes Retrieved	CRM (cm)	DRM (cm)	Anastomotic Leak Rate (%)	Erectile Dysfunction	Fecal Incontinence
1. Park (2012)	*da Vinci*	40	Not Reported	3.6/3.5[1]	0	12.9	6.2 mm	1.4	7.5	11.6/13.0*	8.2/7.8[2]
	Lap	40		5.5/3.2[1]	0	13.3	6.9 mm	1.3	5	7.6/9.0*	11.2/8.4[2]
2. Kim (2014)	*da Vinci*	108	Not Reported		0	18.6	0.9%[4]	1.4	4.6	12.5[3]	12.5/7.7[5]
	Open	114			N/A	16.7	0%[4]	1.2	4.4	34.1[3]	14.2/10.3[5]

*IIEF-5 at 3 and 6 months

[1] IPSS at 3 and 6 months

[2] Wexner Scores at 3 and 6 months

[3] Sexual dysfunction represented >1/3 functional impairments of erectile or ejaculatory potency in male patients aged ≤ 65 years. These parameters were assessed in 40 patients (RA group) and 44 patients (open group), respectively, at 6 months after surgery or chemoradiotherapy.

[4] CRM involvement, ≤1 mm

[5] Assessed at 6 and 12 months